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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,845

10/29/2003

Steven Savage

57173/1301

7833

7590

08/09/2006

Kramer Levin Naftalis & Frankel LLP  
919 Third Avenue  
New York, NY 10022

EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,845	<b>Applicant(s)</b> SAVAGE ET AL. ✓	
	<b>Examiner</b> Phillip Gray	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 36-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/11/05</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action is in response to applicant's communication of 6/19/06. Currently claims 17-20 and 36-42 are pending and rejected below. Applicant previously cancelled 1-16 and 21-35.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-20 and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandmore et al. (U.S. Patent Number 6,059,760). Sandmore discloses a cannula having a reverse flow tip (see figures 1-3 and 12-19).

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Sandmore discloses a catheter for use in a medical procedure, with an elongate tubular structure (36, 46, 38, 45, 28) (fully capable of meeting the size, flow rate), elastic restrictor, and plurality of stem section hole openings formed on the side walls (see elements 100 of figures 12-19) angled toward the proximal end of the catheter for a retrograde fluid stream. Sandmore discloses a hub section (42), a shaft section (36), and a stem section (22), and distal tip with a small opening comprising an elastic restrictor (138,100) and is fully capable, or in the alternative an obvious configuration to one of ordinary skill in the art, of providing a variable amount of fluid force restriction based upon a fluid flow rate through said catheter assembly, such that the forces resulting from the flow is substantially balanced or substantially zero fluid force in all directions (see paragraphs at column 8 through 9). Sandmore discloses that the distal end of the catheter is made of a material that is softer than a material of the proximal end (see paragraphs beginning at column 3). Further the Sandmore tubular structure is fully capable of enabling fluid flow rates in a range of approximately 0 to 40 ml/sec without failure of said tubular structure.

Concerning the size requirements of a device with no greater or about 4 French, diameter approximately 0.305 mm or 0.33 mm, and length of 1.22 mm (claims 17,19-20,42). Sandmore discloses the claimed invention except for explicitly teaching the exact size parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a device with no greater or about 4 French, diameter approximately 0.305 mm or 0.33 mm, or a length of 1.22 mm, since such a modification would have involved

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a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

It is examiners position that the size requirements, flow rate requirements, and balanced fluid forces are taught by Sandmore, but in the alternative it would have been an obvious modification to one having ordinary skill in the art at the time the invention was made, to have the specific size requirements (see discussion below), flow rate of approximately 0 to 40 ml/sec, and the balanced/zero fluid force function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*PLS*

PAG

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*